OCT 1 0 2001

Wiener lab.
Especialidades para Laboratorios Clínicos
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Section 6 – Summary

510(k) Summary
"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"

"The assigned 510(k) number is: K012065 **"**

Introduction	According to the requirements of 21 CFR 862.1580, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.
6-1 Submitter Name, Address, Contact	Wiener Laboratorios S.A.I.C. Riobamba 2944 2000 – Rosario – Argentina Tel: 54 341 4329191 Fax: 54 341 4851986 Contact person: Viviana Cétola Date Prepared: March 19, 2001

K012065

6-2 Device Name

Proprietary name: Wiener lab. CREATININA CINETICA AA
Common name: Creatinine test system

Classification name: Alkaline picrate, colorimetry, creatinine, CGX, as per 21 CFR section 862.1225.

Device Class II

6-3 Predicate Device

We claim substantial equivalence to the currently marketed "RANDOX CREATININE" Test system (Cat. N° CR510) for the serum / plasma application and "DMA CREATININE" Test system (Cat. N° 1430) for the urine application.

6-4 Device Description

The Creatinine assay is a clinical chemistry assay in which the creatinine in the sample, at an alkaline pH, reacts with picrate to form a creatinine-picrate complex. The rate of increase in absorbance at 500 nm due to the formation of this complex is directly proportional to the amount of creatinine in the sample

6-5 Intended Use

The CREATININA CINETICA AA test system is a device to measure creatinine levels in human serum, plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as calculation basis for measuring other urine analytes.

6-6 Equivalencies and Differences

The CREATININA CINETICA AA test system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed RANDOX CREATININE test system for the serum / plasma application and DMA CREATININE test system for the urine application.

The following table illustrates the similarities and differences between the WIENER LAB CREATININA CINETICA AA test system and the currently marketed RANDOX CREATININE test system.

	RANDOX Test System	WIENER LAB. Test System
Intended Use	Quantitative determination of creatinine in human serum and plasma.	Quantitative determination of creatinine in human serum, plasma and urine.
Test Principle	The Creatinine assay is a clinical chemistry assay in which the creatinine in the sample, at an alkaline pH, reacts with picrate to form a creatinine-picrate complex. The rate of increase in absorbance at 500 nm due to the formation of this complex is directly proportional to the amount of creatinine in the sample.	
Essential Components	Picric acid and NaOH	
Reagents	R1: Picric acid / Surfactant R2: NaOH	R1: Picric acid R2: Carbonate / NaOH
Preparation of Working Reagent	Mixture of R1 and R2 (1:1)	Mixture of R1 and R2 (1:1) or they can be used separately.
Working Reagent Stability	Stable 3 days at 15-25°C in closed plastic bottle	Stable 7 days at room temperature in closed plastic bottle and 24 hours on autoanalyzer
Sample	Human serum and plasma.	Human serum, plasma and urine.
Working Temperatures	25 - 30 - 37°C	
Wavelength of reading.	490-510 nm	
Calibrator and Serum Controls	Available – provided separately	

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	RANDOX Test System	WIENER LAB. Test System
Linearity	10 mg/dl	20 mg/dl
Minimum Detection Limit	Not specified	0.012 mg/dl
Expected Values	Serum (mg/dl) Male: 0.6-1.1 Female: 0.5-0.9	Serum 0.8-1.4 mg/dl Urine 0.8-2.0 g/24hs E.C.C. 71-135 ml/min until 60 years
Within-run Precision	No stated in insert.	Normal Serum Control: CV = 1.0% Abnormal Serum Control: CV = 0.6% Low Level Urine CV = 0.4% High Level Urine CV = 0.5%
Total Precision	No stated in insert.	Normal Serum Control: CV = 1.7% Abnormal Serum Control: CV = 1.0% Low Level Urine CV = 0.7% High Level Urine CV = 1.1%

The following table illustrates the similarities and differences between the WIENER LAB CREATININA CINETICA AA test system and the currently marketed DMA CREATININE test system.

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	DMA Test System	WIENER LAB. Test System
Intended Use	Quantitative determination of creatinine in human serum and urine.	Quantitative determination of creatinine in human serum, plasma and urine.
Test Principle	The Creatinine assay is a clinical chemistry assay in which the creatinine in the sample, at an alkaline pH, reacts with picrate to form a creatinine-picrate complex. The rate of increase in absorbance at 500 nm due to the formation of this complex is directly proportional to the amount of creatinine in the sample	
Essential Components	Picric acid and NaOH	
Reagents	R2: Picric acid R1: NaOH, sodium borate and surfactant	R1: Picric acid R2: Carbonate / NaOH
Preparation of Working Reagent	Mixture of R1 and R2 (1:1)	Mixture of R1 and R2 (1:1) or they can be used separately.
Working Reagent Stability	Stable 14 days at 15-30°C in closed plastic bottle	Stable 7 days at room temperature in closed plastic bottle and 24 hours on autoanalyzer
Sample	Human serum and urine	Human serum, plasma and urine
Working Temperatures	30 - 37°C	25 - 30 - 37°C
Wavelength of reading.	490-510 nm	
Calibrator and Serum Controls	Available – provided separately	
Linearity	20 mg/dl	20 mg/dl

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	DMA Test System	WIENER LAB. Test System
Minimum Detection Limit	0.06 mg/dl	0.012 mg/dl
Expected Values	Serum 0.4-1.6 mg/dl Urine 0.6-1.6 g/24hs E.C.C. Males: 85-125 ml/min Females: 75-115 ml/min	Serum 0.8-1.4 mg/dl Urine 0.8-2.0 g/24hs E.C.C. 71-135 ml/min until 60 years
Within-run Precision	Normal Serum Control: CV = 2.9% Abnormal Serum Control: CV = 1.3%	Normal Serum Control: CV = 1.0% Abnormal Serum Control: CV = 0.6% Low Level Urine CV = 0.4% High Level Urine CV = 0.5%
Total Precision	Normal Serum Control: CV = 4.2% Abnormal Serum Control: CV = 1.7%	Normal Serum Control: CV = 1.7% Abnormal Serum Control: CV = 1.0% Low Level Urine CV = 0.7% High Level Urine CV = 1.1%

6-7 Conclusion Above mentioned data show substantial equivalency to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 0 2001

Dr. Viviana Cetola
QC/QA Manager
Wiener Laboratorios S. A. I. C.
Riobamba 2944
Rosario, Santa Fe
Argentina

Re: k012065
Trade/Device Name: Creatinina Cinetica AA
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: JFY
Dated: August 30, 2001
Received: September 10, 2001

Dear Dr. Cetola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012065

510(k) Number (if known): K012065

Device Name: Wiener lab.
Creatinina Cinética AA

Indications For Use:

The "Wiener lab. Creatinina cinética AA" creatinine test system is a device intended to measure creatinine levels in plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Kesia Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012065

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

SK-24